



Septerna Highlights Pipeline Progress and Reports Fourth Quarter and Full Year 2025 Financial Results

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Compelling Phase 1 Data for SEP-631 (MRGPRX2 NAM) in Healthy Volunteers Support Phase 2b Development, Initially in Chronic Spontaneous Urticaria (CSU) in Second Half of 2026

Advancing SEP-479 (PTH1R Agonist) Toward Phase 1 Initiation in First Half of 2026

Cash Runway Expected to Support Operating Plans at Least into 2029

SOUTH SAN FRANCISCO, Calif., March 09, 2026 (GLOBE NEWSWIRE) -- Septerna, Inc. (Nasdaq: SEPN), a clinical-stage biotechnology company pioneering a new era of G protein-coupled receptor (GPCR) drug discovery, today highlighted pipeline progress and anticipated milestones and reported financial results for the fourth quarter and full year ended December 31, 2025.

"We made significant strides advancing our pipeline in the past year, and 2026 has already delivered a meaningful milestone with positive Phase 1 results for SEP-631," said Jeffrey Finer, M.D., Ph.D., chief executive officer and co-founder of Septerna. "These results demonstrate clinical proof-of-mechanism and validate the ability of our Native Complex Platform® to uncover novel mechanisms of action and rapidly generate differentiated oral small molecules for historically challenging GPCRs. With SEP-479 approaching Phase 1 initiation in the coming months, SEP-631 poised for Phase 2 development in the second half of the year, and additional programs progressing behind them, we believe 2026 will be a year of strong progress for Septerna and for the patients we are committed to serving."

Recent Pipeline Progress and Anticipated Milestones

- **SEP-631 MRGPRX2 NAM for Mast Cell Diseases:**
 - In March 2026, Septerna [presented](#) positive results from its Phase 1 clinical trial evaluating SEP-631, its potent, selective and insurmountable oral small molecule MRGPRX2 negative allosteric modulator (NAM) and outlined its initial Phase 2 development strategy. Key findings include:
 - **Safety:** SEP-631 was well-tolerated at all doses studied with an adverse event profile comparable to placebo.
 - **Pharmacokinetics (PK):** SEP-631 demonstrated a PK profile supportive of convenient once-daily oral dosing without food restrictions.
 - **Pharmacodynamics (PD):** SEP-631 produced robust suppression of wheal formation across evaluated dose levels, with complete inhibition observed at doses as low as 10 mg once daily following the 10 µg/mL icatibant challenge. Following the 100 µg/mL icatibant challenge, inhibition was dose-dependent, with progressively greater suppression observed at increasing SEP-631 doses with near to complete inhibition achieved at 90 and 200 mg once daily.
 - Septerna plans to initiate a Phase 2b trial of SEP-631 in CSU in the second half of 2026 following completion of long-term toxicology studies, with an open-label study in chronic inducible urticaria (CIndU) patients with symptomatic dermatographism to follow. Septerna is also evaluating additional mast cell-driven diseases with high unmet need and MRGPRX2 expression on tissue-resident mast cells.
- **SEP-479 PTH1R Agonist for Hypoparathyroidism:**
 - Septerna has completed IND-enabling studies for SEP-479, its potent and selective oral small molecule PTH1R agonist, and is on track to initiate a Phase 1 clinical trial in the first half of 2026.
- **TSHR NAM Program:**
 - Septerna continues to progress toward development candidate selection for its TSHR NAM program, with the goal of delivering a potential disease-modifying oral treatment for Graves' disease and thyroid eye disease.
- **Discovery Programs:**
 - Septerna also continues to advance discovery-stage programs utilizing its Native Complex Platform® across multiple therapeutic areas.

Business Highlights

- In January 2026, Septerna [appointed](#) Mark A. Wilson as chief legal officer. Mr. Wilson is an accomplished pharmaceutical and biotech executive with more than 25 years of experience across intellectual property, corporate legal, strategic collaborations and corporate governance matters.

Fourth Quarter and Full Year 2025 Financial Results

- **Cash Position:** Cash, cash equivalents, and marketable securities totaled \$548.7 million as of December 31, 2025, compared to \$420.8 million as of December 31, 2024. During 2025, Septerna received a \$195.0 million upfront payment from Novo Nordisk and a \$12.5 million milestone payment from Vertex. Septerna expects its existing cash runway to fund operations at least into 2029.
- **Revenue:** Revenue was \$24.1 million for the fourth quarter of 2025 and \$46.0 million for the full year ended December 31, 2025, compared to \$0.2 million for the fourth quarter of 2024 and \$1.1 million for the full year ended December 31, 2024.
 - Revenue for the fourth quarter of 2025 included the amortization of \$14.0 million of the \$195.0 million upfront payment received from Novo Nordisk in July 2025, as well as \$10.1 million for research services associated with the collaboration.
 - Revenue for the full year ended December 31, 2025, included the amortization of \$26.8 million of the \$195.0 million upfront payment received from Novo Nordisk in July 2025, as well as \$18.6 million for research services associated with the collaboration.
- **R&D Expenses:** Research and development (R&D) expenses were \$31.9 million for the fourth quarter of 2025 and \$97.6 million for the full year ended December 31, 2025, compared to \$19.3 million for the fourth quarter of 2024 and \$65.3 million for the full year ended December 31, 2024.
- **G&A Expenses:** General and administrative (G&A) expenses were \$8.3 million for the fourth quarter of 2025 and \$29.2 million for the full year ended December 31, 2025, compared to \$5.6 million for the fourth quarter of 2024 and \$16.6 million for the full year ended December 31, 2024.
- **Net Loss:** Net loss was \$10.7 million for the fourth quarter of 2025 and \$48.9 million for the full year ended December 31, 2025, compared to net losses of \$20.7 million for the fourth quarter of 2024 and \$71.8 million for the full year ended December 31, 2024.

About Septerna

Septerna, Inc. is a clinical-stage biotechnology company with a world-class team of GPCR experts and drug developers advancing cutting-edge science to unlock the full potential of GPCR therapies for patients with significant unmet needs. The company's proprietary Native Complex Platform[®] is designed to enable new approaches to GPCR drug discovery and has led to the development of a diverse pipeline of novel oral small molecule drug candidates. Septerna is advancing programs in endocrinology, immunology and inflammation, metabolic diseases and additional therapeutic areas, both independently and with partners. For more information, please visit www.septerna.com.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including, without limitation, implied and express statements about Septerna's beliefs and expectations regarding: the continued advancement of SEP-631, including the plan to initiate a Phase 2b clinical study in CSU in the second half of 2026 subject to the successful completion of long-term preclinical toxicology studies; the role of MRGPRX2 in mast cell-driven diseases; the potential of SEP-631 to provide a convenient oral treatment option for patients with CSU and other mast cell-driven diseases; expectations regarding the anticipated once-daily dosing frequency of SEP-631; the ability of the SEP-631 Phase 1 safety and efficacy observations to successfully translate into clinical outcomes in patients; the continued advancement of SEP-479, including the plan to initiate a Phase 1 clinical study in the first half of 2026; the continued development of its TSHR NAM program; the advancement of its discovery-stage programs across multiple therapeutic areas; the potential of its proprietary Native Complex Platform[®]; the size and growth potential of the markets for its current and future product candidates; its expectations regarding strategic plans for its business, product candidates, and technology; its expectations regarding the company's uses of capital, expenses and financial results, including its expected cash runway at least into 2029; and the scope of protection it is able to establish and maintain for intellectual property rights covering its Native Complex Platform[®] and its product candidates. The words "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "might," "objective," "ongoing," "plan," "predict," "project," "potential," "should," or "would," or the negative of these terms, or other comparable terminology are intended to identify forward-looking statements, although not all forward looking statements contain these identifying words.

Any forward-looking statements in this press release are based on management's current expectations and beliefs and are subject to a number of risks, uncertainties and important factors that may cause actual events or results to differ materially from those expressed or implied by any forward-looking statements contained in this press release, including, without limitation, risks associated with: Septerna's product candidates successfully entering and advancing through clinical trials (including those for SEP-631) including uncertainties related to opening INDs and obtaining other regulatory approvals; risks related to clinical development outcomes including unexpected safety or efficacy findings; the results of preclinical studies including the long-term toxicology studies for SEP-631, or clinical studies not being predictive of future clinical outcomes; risks related to the timing of initiating clinical studies and future availability of clinical data; the scope of protection Septerna is able to establish and maintain for intellectual property rights covering its Native Complex Platform[®] and its product candidates; and Septerna's ability to identify and enter into future license agreements and collaborations; and general economic, industry and market conditions. These and other risks and uncertainties are described in greater detail in the section entitled "Risk Factors" in Septerna's Annual Report on Form 10-K for the year ended December 31, 2025, as well as any subsequent filings with the Securities and Exchange Commission. In addition, any forward-looking statements represent Septerna's views only as of today and should not be relied upon as representing its views as of any subsequent date. Septerna explicitly disclaims any obligation to update any forward-looking statements subject to any obligations under applicable law. No representations or warranties (expressed or implied) are made about the accuracy of any such forward-looking statements.

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SEPTERNA, INC.

Condensed Statements of Operations *(In thousands, except for share and per share data)* *(Unaudited)*

	Three Months Ended		Years Ended December 31,	
	2025	2024	2025	2024
Revenue	\$ 24,118	\$ 212	\$ 45,951	\$ 1,075
Operating expenses:				
Research and development	31,861	19,317	97,584	65,337
General and administrative	8,280	5,613	29,164	16,561
Gain on sale of non-financial asset	—	—	(12,500)	—
Total operating expenses	40,141	24,930	114,248	81,898
Loss from operations	(16,023)	(24,718)	(68,297)	(80,823)
Interest income and other expense, net	5,297	3,890	19,430	8,527
Provision (benefit) for income taxes	12	(160)	12	(498)
Net loss	\$ (10,738)	\$ (20,668)	\$ (48,879)	\$ (71,798)
Net loss per share, basic and diluted	\$ (0.24)	\$ (0.64)	\$ (1.10)	\$ (7.26)
Weighted-average shares outstanding, basic and diluted	44,579,697	32,383,314	44,258,338	9,891,126

Condensed Balance Sheets *(In thousands)* *(Unaudited)*

	December 31,	September 30,	December 31,
	2025	2025	2024
Cash, cash equivalents and marketable securities	\$ 548,658	\$ 561,558	\$ 420,789
Working capital ⁽¹⁾	324,033	416,399	343,975
Total assets	596,187	606,653	456,554
Total liabilities	214,261	217,922	36,507
Additional paid-in capital	548,517	544,826	538,321
Accumulated deficit	(167,253)	(156,515)	(118,374)
Total stockholders' equity	\$ 381,926	\$ 388,731	\$ 420,047

1. Working capital is defined as total current assets less total current liabilities. See our financial statements and the related notes thereto included in our Annual Report on Form 10-K for the year ended December 31, 2025, for further details regarding our current assets and current liabilities.